JUL 16 2004

K041792

510(K) SUMMARY

Applicant /Manufacturing Site:

IBt s.a.
Zone Industrielle C
7180 Seneffe – Belgium
Tel: (+32) 64 / 520 811
Fax: (+32) 64 / 520 801

Establishment Registration Number: 9031509 (IBt s.a.)
Contact Person IBt s.a.: Sylviane Berger, Management Representative
E-mail: sberger@brachytherapy.be

Official Correspondent:

IBt, Inc.
6000 Live Oak Parkway, Suite 107
Norcross, GA 30093
Tel: (770) 582 0662
Fax: (770) 582 0657

Establishment Registration Number: 9035105 (IBt, Inc.)
Contact Person IBt, Inc.: Ruth Feicht, President
E-mail: rfeicht@ibt4seeds.com

Device Information

Trade Name: EZ-Pak (EZ-Pak™ is a Trademark of IBt s.a.)
Model Number: Not Applicable
Common Name of Device: Preloaded needles / cartridges, sealed source; seed; interstitial implant

Type of 510(k) Submission: Special 510(k) Device Modification

Classification Information

Classification: Radionuclide Brachytherapy Source Class II device
Class of Device: 21 CFR 892.5730, Class II
Product Code: 90-KXK

Intended Use

EZ-Pak™ is a packaging change to InterSource^{103} (#K973328), InterSource^{125} (#K9984235) and InterStrand® (#K011155). There is no change in the intended use of these cleared sources. Please see the referenced Premarket Notification documents for Statements of Intended Use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2004

Ms. Ruth Feicht
President
International Brachytherapy, Inc.
6000 Live Oak Parkway, Suite 107
NORCROSS GA 30093

Re: K041702
Trade/Device Name: EZ-Pak Preload Needles
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: 90 KXK
Dated: June 21, 2004
Received: June 23, 2004

Dear Ms. Feicht:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k041702

Device Name: EZ-Pak Preloaded Needles

Indications For Use:

The sources in EZ-Pak Preloaded Needles are indicated for interstitial implantation of select localized tumors with low to moderate radiosensitivity. They are used either as primary treatment for tumors such as those of the head, lung, neck, pancreas, prostate, and unresectable tumors, or for residual disease after excision of the primary tumor.

The source in EZ-Pak Preloaded Needles are indicated for use concurrent with or at the completion of other treatment modalities, such as external beam radiation therapy or chemotherapy.

Prescription Use / AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041702